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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/160,076	09/24/1998	DAVID W. SCOTT	308072000110	5918

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1633	32

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/160,076	SCOTT ET AL.	
	Examin r	Art Unit	
	Michael Wilson	1633	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-21-01, paper number 28, has been entered.

Claims 31-51 have been canceled. Claims 52-68 have been added. Claims 52-68 are pending and under consideration in the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 9-21-01, paper number 28, and the declaration by David Scott, paper number 30, have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

1. Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The limitation of ATCC 69555 is new matter. The specification as originally filed did not teach the ATCC number and the deposit document filed 8-26-99 does not state the name of

specimen ATCC 69555. Therefore, it cannot be determined that ATCC 69555 relates to the instant application.

2. Claims 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 65 and 66 are directed toward a cell transfected with a vector encoding a fusion protein for inducing tolerance to an antigen, wherein the fusion protein comprises an immunoglobulin and a mammalian antigen, an autoantigen or an allergenic antigen. At the time of filing nucleic acids encoding mammalian antigen, an autoantigen or an allergenic antigen, such as clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, histocompatibility proteins, pollen proteins, ragweed proteins and dust mite proteins were known in the art (See Exhibit A of applicants response). The art did not teach how to introduce a nucleic acid encoding any such fusion protein into a cell and administer the cell to a host such that tolerance to the antigen was obtained.

Applicants argue the specification teaches how to select the antigen of interest. Applicants argument is not persuasive. The specification does not teach administering a cell to a host, wherein said cell is transfected with a vector encoding a fusion protein comprising an immunoglobulin and a mammalian antigen, an autoantigen or an allergenic antigen, such that tolerance to the antigen is obtained.

Applicants argue the declaration provides written description for a composition that induces tolerance. Applicants argument is not persuasive because the teachings in the declaration do not correlate to the specification as originally filed. The specification as originally filed does not teach the specific combination of transfecting B-cell blasts with a vector encoding IgG/full length MBP protein and administering the cells to allergic encephalitis (EAE) mice intravenously. Lambda repressor cI protein and ovalbumin are not mammalian antigens, autoantigens or allergenic antigens as claimed because they are derived from bacteriophage and chickens, respectively. GAD, insulin B chain and IRBP are not disclosed in the specification as originally filed. Therefore, the declaration does not correlate to the specification as originally filed and does not indicate the specification as originally filed provided written description for the claims.

An adequate written description of a composition requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the composition itself that has the desired function. It is not sufficient to define a composition solely by its principal biological property, i.e., inducing tolerance to an antigen, because disclosure of no more than that is simply a wish to know the identity of cells that induce tolerance. Naming a product generically, in the absence of knowledge as to what combination of elements are required to induce tolerance, is not a description of that material. Thus, claiming all pharmaceutical compositions comprising cells transfected with the vectors of claim 52-55 that induce tolerance without defining the combination of cell, tolerogenic epitope

and immunoglobulin required to induce tolerance is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

3. Claims 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 65 and 66 are directed toward a cell transfected with a vector encoding a fusion protein for inducing tolerance to an antigen, wherein the fusion protein comprises an immunoglobulin and a mammalian antigen, an autoantigen or an allergenic antigen. At the time of filing nucleic acids encoding mammalian antigen, an autoantigen or an allergenic antigen, such as clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, histocompatibility proteins, pollen proteins, ragweed proteins and dust mite proteins were known in the art (See Exhibit A of applicants response). The art did not teach how to introduce a nucleic acid encoding any such fusion protein into a cell and administer the cell to a host such that tolerance to the antigen was obtained. The specification does not teach administering a cell to a host, wherein said cell is transfected with a vector encoding a fusion protein comprising an immunoglobulin and a mammalian antigen, an autoantigen or an allergenic

antigen, such that tolerance to the antigen is obtained. Therefore, applicants do not enable the claims.

Applicants argue the declaration by Dr. Scott enables obtaining tolerance. Applicants argument is not persuasive. The specification as originally filed does not teach the specific combination of transfecting B-cell blasts with a vector encoding IgG/full length MBP protein and administering the cells to allergic encephalitis (EAE) mice intravenously. Lambda repressor cI protein and ovalbumin are not mammalian antigens, autoantigens or allergenic antigens as claimed because they are derived from bacteriophage and chickens, respectively. GAD, insulin B chain and IRBP are not disclosed in the specification as originally filed. Therefore, the declaration does not correlate to the specification as originally filed and is not adequate to enable the claims.

4. Claims 52-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52-54 are indefinite because the phrase "polypeptide or portion thereof containing at least one epitope" is unclear. It is unclear if "containing at least one epitope" refers to just the "portion thereof" or to the polypeptide and the "portion thereof."

Claim 55 is indefinite because the phrase "polypeptide, or portion thereof, of an allergen comprising at least two epitopes" is unclear. It is unclear if "comprising at least two epitopes" refers to just the polypeptide or to the polypeptide and the "portion thereof."

Claim 52 is indefinite because the metes and bounds of the proteins encompassed in 2) cannot be determined. It is unclear whether the protein has 1 or 2 epitopes because it is unclear whether "comprising at least two epitopes" relates to just allergen proteins or to mammalian proteins, autoantigenic proteins and allergen proteins.

Claim 52 is indefinite because using "mammalian antigenic polypeptide" and "autoantigenic polypeptide" in the same Markush group is indefinite. It is unclear if applicants believe these to be separate entities or if there is overlap. The terms are not defined in the specification and are relative terms that would have various meanings in the art. Therefore, the metes and bounds of the proteins encompassed by the claim cannot be determined.

Claims reciting "mammalian antigenic polypeptide" are indefinite because it is unclear if the phrase is intended to mean mammalian polypeptides that are antigenic or polypeptides that are antigenic in mammals. The latter would include viral proteins, pollen, etc.

Claims 52, 54, 62 are indefinite because the metes and bounds of proteins encompassed by the term "autoantigenic" cannot be determined. Applicants argue that the term has an art recognized meaning which is "any tissue constituent that evokes an immune response to the host's tissues." Applicants argument is not persuasive. Proteins capable of evoking an immune response within a host include factor VIII, acetylcholine receptors, collagen, MBP, thyroglobulin and MHC molecules. However, the term "autoantigenic" describes proteins relative to their host. Would factor VIII isolated from healthy individuals be included in the claim or would factor VIII have to be isolated from a person who had an autoimmune response against it? Thus, it is unclear

if the term refers only to protein isolated from a host having an autoimmune response against that protein or if it can it be also be isolated from a healthy individual.

Claim 58 is indefinite because it is unclear if the claim encompasses two copies of the vector or if the vector comprises two copies of the nucleic acid sequence encoding the fusion protein. It is unclear if the two copies are operably linked to one promoter or if each copy is operably linked to a promoter.

Claim 60 is indefinite because the term "characteristics" is not defined in the specification and may have various meanings in the art as stated in the previous office action. It is unclear whether applicants intend to claim a physical characteristic or a function.

The term "histocompatibility antigen" is indefinite (claim 62). It is unclear whether applicants intend to claim a particular epitope derived from a histocompatibility molecule such as B7 or whether applicants intend to claim an epitope derived from a protein involved in histocompatibility such as antibodies involved in tolerance. Applicants argue "[i]n the context of an autoantigen, the meaning of the term 'histocompatibility antigen' would also be known to the person of skill in the art, and thus is not indefinite." Applicants argument is not persuasive because the term "autoantigen" remains indefinite and because it is unclear what proteins would be encompassed by "autogenic histocompatibility antigens" (i.e. antibodies?).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 52-55, 58 and 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Zanetti (US Patent 5,508,386, April 16, 1996).

Zanetti specifically taught a vector encoding a fusion protein comprising an immunoglobulin and an antigenic epitope of a plasmodium protein. J588 cells were transfected with the vector (col. 6). The plasmodium protein is considered an allergen protein because it induces an immune response in humans. J588 cells are bone marrow tumor cells. The plasmodium protein is a "mammalian antigenic polypeptide" because it is a protein that is antigenic in mammals.

Zanetti as a whole taught a vector encoding a fusion protein comprising an immunoglobulin and an antigen (claim 1) and cells transfected with the vector (claim 4), wherein the antigen is associated with autoimmune disease or an allergen (col. 3, lines 39-54, especially lines 41 and 42). Antigens associated with autoimmune disease are considered "autoimmunogenic". They are also "mammalian antigenic polypeptides" because they are derived from mammals. The limitation of "syngeneic" is an intended use because the

composition may not be administered; however, the J588 would be syngeneic to some individuals. Zanetti claims priority to US Patent 5,583,202, filed Dec. 16, 1994, which also supports the vector and is a continuation of 07/947,521 filed 9-18-89. Thus, Zanetti taught all the limitations of the claims.

6. Claims 52-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Romet-Lemonne et al. (US Patent 6,258,358, July 10, 2001) as supported by Romet-Lemonne et al. US Patent 6,248,332, June 19, 2001).

Romet-Lemonne taught making a nucleic acid sequence encoding a fusion protein comprising an immunoglobulin and an antigen (col. 6, line 58-col. 7, line 5; claims 12 and 13). The antigen is a pollen, ragweed or HIV antigen (col. 6, line 30; claim 5). Thus, Romet-Lemonne teaches all the limitations of the claims. While '358 is a divisional application of '332, the disclosures are essentially equivalent (see col. 6, lines 30 and 61). Therefore, '332 provides support for the fusion protein made by genetic engineering. Since '332 is a continuation of an application filed April 27, 1992, the teachings in '358 regarding the fusion protein made by genetic engineering have priority back to at least April 27, 1992.

7. Claims 52-55, 58, 59, 61, 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Zambidis of record (Zambidis et al., Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251).

Zambidis taught the cell line J588L transfected with a vector encoding a fusion protein comprising an IgG heavy chain with bacteriophage λ cl protein on the N-terminus. The λ cl

protein is an allergen because it induces an immune response. The λ cl protein is a mammalian antigenic polypeptide because it is antigenic in mammals. The λ cl protein contains a B-cell epitope and a T-cell epitope (line 11) which is equivalent to two epitopes. J588L is a myeloma cell line which is a bone marrow tumor cell line. The constructs used for electroporation are in a pharmaceutically acceptable excipient. The intended uses, "pharmaceutical composition" and "suitable for introduction into an individual," in claim 65 do not bear patentable weight because the composition may be used *in vitro* and may not have a pharmacological effect. The limitation of "syngeneic" is an intended use because the composition may not be administered; however, the J588L would be syngeneic to some individuals.

Applicants argue the λ cl protein is not an antigenic polypeptide of an allergen. Applicants argument is not persuasive because λ cl protein would be recognized as a foreign, bacterial protein in mammals and induce an immune response.

Claim Rejections - 35 USC § 103

8. Claims 52-55, 58 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanetti (US Patent 5,508,386, April 16, 1996) in view of GenBank Record No. gi:485370; gi:169626; gi:166436; gi:387591; gi:217305; gi:182802; 32323; gi:30101; gi:187400; gi:37173; gi:188229; gi:529041 or gi:575493.

Zanetti taught a vector encoding a fusion protein comprising an immunoglobulin and an antigen (claim 1) and cells transfected with the vector (claim 3). Zanetti did not teach the

antigens were pollen proteins, ragweed proteins, dust mites proteins, factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility proteins. However, at the time of filing, nucleic acids encoding pollen proteins, ragweed proteins, dust mites proteins, factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility proteins were known in the art (GenBank Record No. gi:485370; gi:169626; gi:166436; gi:387591; gi:217305; gi:182802; 32323; gi:30101; gi:187400; gi:37173; gi:188229; gi:529041 and gi:575493).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the vector of Zanetti using the nucleic acids encoding pollen proteins, ragweed proteins, dust mites proteins, factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility proteins known in the art. Motivation is provided by Zanetti by suggesting the antigen is associated with autoimmune disease or an allergic protein (col. 3, lines 39-54, especially lines 41 and 42). One of ordinary skill in the art at the time the invention was made would have been motivated to use the nucleic acids encoding pollen proteins, ragweed proteins, dust mites proteins, factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility proteins known in the art to make a fusion protein to target the epitope to cells using the immunoglobulin (col. 3, line 25).

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

9. Claims 52, 55-59, 61, 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zambidis (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) in view of Zanetti (Jan. 30, 1992, Nature, Vol. 355, pages 476-477) and Chambers (Feb. 1992, PNAS, USA, Vol. 89, pages 1026-1030).

Zambidis taught the cell line J588L transfected with a vector encoding a fusion protein comprising an IgG heavy chain with bacteriophage λ cl protein on the N-terminus (see the discussion above in the 102 rejection). Zambidis did not teach the vector was a retroviral vector. However, at the time of filing, Chambers taught expressing proteins in lymphoid cells using retroviral vectors (page 1029, column 2, "discussion").

In response to applicant's argument that Zambidis, Zanetti and Chambers are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, one of ordinary skill in the art at the time the invention was made would have recognized the T-cells and PBL expressing IL-6 of Chambers correlated to J588L cells expressing a IgG/antigen fusion protein of Zambidis because IL-6 and IgG fusion proteins are both biologically active proteins and because Zanetti taught T-cells and PBL expressing a fusion protein comprising an antibody and an antigen. Thus, Zanetti provides the nexus between Zambidis and Chambers.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one of ordinary skill in the art at the time the invention was made to transfect J588L cells with a vector encoding the fusion protein as taught by Zambidis using the retroviral vector of Chambers. At the time of filing, it was commonplace for the ordinary artisan to use different vectors to express proteins. One of ordinary skill in the art at the time the invention was made would have been motivated to use a retroviral vector to obtain expression of biologically active protein in J588L. Further motivation is provided by Chambers who taught retroviral vectors encoding biological proteins produce biologically active levels of the proteins in lymphoid cells. One of ordinary skill in the art at the time the invention was made would have recognized that J588L were lymphoid cells and that retroviral vectors could be used to express the fusion proteins in J588L.

Applicants argue one of ordinary skill would not have had a reasonable expectation of success in obtaining tolerance in view of the teachings of Zambidis. Applicants argument is not persuasive. Claims 52, 55-59 and 61 do not require tolerance. The limitations of "a pharmaceutical composition for inducing tolerance" and "suitable for introduction into an

individual," in claims 65-68 do not bear patentable weight because the composition may be used *in vitro* and may not have a pharmacological effect. Therefore, all that is required is a vector or cells comprising the vector which the ordinary artisan at the time of filing would have had a reasonable expectation of making and using *in vitro*.

Specification

10. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequences on page 31 and 35 have two sequences but only one sequence listing. The sequence in Fig. 1 does not have a description of the SEQ ID NO(s). Because Fig. 1 is unclear, it cannot be determined how many sequences are disclosed (each will require a SEQ ID NO). Clarification is required**. Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with sequence rules in response to this action will be considered non-responsive.

The description of Fig. 1 should begin "FIGURE 1A and 1B:".

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER